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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/500,077 | 06/23/2004 | Stephen Proulx | MCA-589A PC/US | 5860 |
| 25182 | 7590 | 09/22/2005 | EXAMINER | |
| MILLIPORE CORPORATION 290 CONCORD ROAD BILLERICA, MA 01821 | | | BOUCHELLE, LAURA A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3763 | |

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/500,077

Applicant(s)

PROULX ET AL.

Examiner

Laura A. Bouchelle

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/23/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 3, 6, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Leason et al (US 5360413). Leason discloses and access device comprising a body 12 having a bore 15 that passes through the entire length of the body, a moveable plunger 18 having a first and second end contained within the bore, wherein the body 12 has a first end 6 and a second end 8, the first end being connected to an upstream component, and the second end being connected to a downstream component. See Figs. 3 and 7. Leason further discloses that when the plunger is in a closed position, the first end of the plunger is in alignment with the face of the body, forming a steamable surface and a sterile barrier for the interior of the body and the downstream components (Col. 3, line 56-68). Leason further discloses that the device is to be used with fluids (see Abstract), fluids inherently being liquids or gases.
3. Regarding claims 6 and 7, Leason's needleless access device allows for sterile to sterile connection as well as sterile to non-sterile connection (Col. 1, lines 50-56).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leason et al in view of Tessman et al (US 6210372). Claim 4 differs from Leason in calling for the device to be formed of plastic. Claim 5 differs in calling for the device to be formed of polyetherimides. Tessman discloses a storage and delivery device for a catheter or needle wherein the device is made using thermoplastics such as polyetherimide that have high hardness and strength and can withstand sterilization (Col. 6, lines 55-60). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to form the device of Leason of a thermoplastic such as polyetherimide so that the device would be able to withstand sterilization.

6. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leason et al in view of Bindokas et al (US 6162206). Claim 8 differs from Leason in calling for the first end to have a liquid impermeable steam resistant face. Claims 9 and 10 differ in calling for the seal to be of a specific plastic or metal foil. Bindokas discloses a resealable access site comprising a body 28 with a bore 29 wherein the first end has a liquid impermeable steam resistant layer 112 attached to it (Col. 9, lines 25-37). Bindokas also calls for the device to be made of polysulfone (Col. 7, line 43). This layer formed of the specified material allows for steam sterilization while

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keeping the opening sealingly closed (Col. 7, lines 34-40). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Leason by adding a steam resistant layer made of polysulfone as taught by Bindokas so that the device can be steam sterilized without opening the seal.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura A Bouchelle
Examiner
Art Unit 3763



NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700